

## **REMARKS**

### **Summary of the Office Action**

The title of the invention has been objected to because not descriptive.

The abstract of the disclosure has been objected to because not descriptive.

Claims 1-18 have been rejected to under 35 U.S.C. § 112, second paragraph, as indefinite.

Claims 1-18 have been rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,066,298 to Hess (“Hess”) in view of U.S. Patent No. 6,110,192 to Ravenscroft et al. (“Ravenscroft”) or, in the alternative, of European Patent No. 0834293 to Almeleh et al. (“Almeleh”).

### **Status of the Application**

Claims 1-20 are pending in the application, of which claims 19-20 have been withdrawn from examination. Claims 1-4 and 9-10 have been amended herein. Therefore, upon entry of the present amendment, claims 1-18 will be subject to examination.

### **In the Specification and Abstract**

The title of the specification, paragraphs 1, 4, 6 and 15 of the specification, and the abstract have been amended to change the recitation “trimming a balloon of a balloon catheter” with “coupling a stent to a balloon.” While Applicants submit that “trimming” may be interpreted consistently with the remainder of the specification and abstract, the amended language has been introduced without restrictive intent in order to expedite allowance of the application.

### **In the Claims**

The preambles of claims 1-18 have been amended to provide recitations consistent with the amendments to the specification.

Concerning the rejections under 35 USC 103(a), Hess teaches a method of compressing a catheter balloon by wrapping it with a tape, but does not teach or suggest “leaving uncompressed portions of the folded balloon between the spaced apart loops of the member wrapped around the folded balloon to form protrusions on the folded balloon,” as claimed in Applicants’ claim 1.

*See*, Hess, col. 3, lines 14-20. Hess also teaches that, once wrapped, the balloon is never unfolded prior to actual use, even after the wrapping is removed, but instead that the balloon is tightly wrapped with a band, heated, then the band is removed, and the balloon, still in folded condition, is inserted into a sheath. *See*, Hess, FIGS. 2-4.

Further, Hess teaches that heat is applied after the balloon has been wrapped and not “heating the balloon during the wrapping,” as claimed in Applicants’ claim 2. *See*, Hess, col. 3, lines 41-44.

Instead, Ravenscroft teaches forming a balloon having ridges perpendicular to a longitudinal axis, which extend around a portion of the perimeter of the balloon and leave a ridge-free longitudinal strip. *See*, Ravenscroft, FIGS. 1-2. Such a ridged configuration is produced by a blow-molding process. *See*, Ravenscroft, col. 5, lines 62-65. The purpose of this configuration is to allow the balloon to fold in an un-inflated condition in book-like fashion. *See*, Ravenscroft, FIGS. 16-19. The method taught by Ravenscroft does not involve “folding the balloon over the catheter by lateral rotation,” “wrapping a member around the folded balloon such that spaced-apart loops of the member wrapped around the balloon compress the folded balloon leaving uncompressed portions of the folded balloon between the spaced apart loops of the member wrapped around the folded balloon to form protrusions on the folded balloon,” “leaving the member wrapped around the balloon for a predetermined period of time,” and “removing the member from the balloon after the predetermined period of time,” as claimed in Applicants’ claim 1.

In the alternative, Almeleh teaches forming protrusions on the surface of a balloon, which, in one embodiment, may be ridge-shaped. *See*, Almeleh, FIG. 3. Almeleh further teaches that the balloon is manufactured by expansion in a heated cavity. *See*, Almeleh, col. 3, lines 10-19. Like Ravenscroft, Almeleh does not teach “folding the balloon over the catheter by lateral rotation,” “wrapping a member around the folded balloon such that spaced-apart loops of the member wrapped around the balloon compress the folded balloon leaving uncompressed portions of the folded balloon between the spaced apart loops of the member wrapped around the folded balloon to form protrusions on the folded balloon,” “leaving the member wrapped around the balloon for a predetermined period of time,” and “removing the member from the balloon after the predetermined period of time,” as in Applicants’ claim 1. Even if Almeleh taught that a stent may be disposed over the balloon, Almeleh is silent as to whether the balloon is folded and how the stent and the balloon are coupled.

Applicants traverse the Examiner's rejection under 35 USC 103(a) and first note that the method taught by Hess does not involve the forming of protrusions, as the Examiner has acknowledged.

The Examiner has asserted that "[t]he desirability of a balloon with protrusions thereon is taught by Almeleh et al ... and also by Ravenscroft et al." Applicants submit that this is not the proper inquiry, because claims 1-18 are directed to a method and not to a product-by-process. Instead, the proper inquiry is whether the method steps are obvious in view of the methods of the prior art. Accordingly, whether the resulting product is obvious or not in view of the prior art is not addressed herein.

The cited combination is not obvious in view of the cited references because a person skilled in the art at the time the invention was made would have been required to combine Hess's method, which is based on a complete wrapping of a folded balloon to produce a reduced cross-section, with steps that require blow-molding (Ravenscroft) or an expansion in a heated mold (Almeleh) to obtain Applicants' method. Clearly, the steps introduced by Ravenscroft or Almeleh are extraneous and even contradictory to Applicants' claimed process.

Further, Hess requires that the balloon be maintained in a folded state until insertion in the sheath, while Applicants' process requires no such step. In fact, Applicants disclose that the balloon may unfold prior to coupling with the stent. See, Applicants, FIG. 2. Applicants' method may cause a balloon to have "wings" with recesses in which the stent is to be lodged, or a balloon with a star-like cross-section, while the disclosures of Ravenscroft and Almeleh relate to balloons having different cross-sections prior to coupling with the stent. For example, FIGS. 6 and 19 of Ravenscroft (and the related descriptions) shows the balloon prior to coupling with the stent, with a configuration different from Applicants'. Instead, Almeleh is silent in this regard, but the figures of Almeleh clearly do not depict Applicants' method.

As the Supreme Court has admonished, "a patent claim cannot be proved obvious merely by showing that the combination of elements was 'obvious to try'." *KSR v. Teleflex*, 550 US \_\_\_\_ (2007). Here, the cited references support a conclusion of non-obviousness because the proposed combination of method steps is not feasible, and because Hess demonstrates that compressing a balloon by wrapping it with tape has been known for at least 16 years and Ravenscroft demonstrates that it has been known for almost a decade that surface protrusions are advantageous, yet no one, other than Applicants, has wrapped a balloon to form the surface protrusions and applied a stent to the resulting configuration.

For at least these reasons, the withdrawal of all rejections is respectfully requested. The dependent claims are further distinguishable from the cited prior art for the additional limitations contained therein, *see*, e.g., the previous discussion related to the heating step of claim 2.

### **Conclusion**

In view of the foregoing remarks, Applicants respectfully submit that the present application is in condition for allowance. Reconsideration and re-examination of the pending claims is respectfully requested.

Dated: January 24, 2007

Respectfully submitted,

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